

REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The August 2, 2005, interview between Examiners Q. Nguyen and D. Nguyen, inventor Steven A. Goldman, M.D., Ph.D., and applicants' undersigned attorney is gratefully acknowledged. The substance of the interview is summarized below. The claims have been limited to the combined use of brain-derived neurotrophic factor and a bone morphogenic protein inhibitor or their encoding nucleic acids which are introduced with a viral vector. This results in the addition of medium spiny neurons. In treating subjects, Huntington's Disease can be delayed. Support for these features of the claimed invention is found in the present application at page 9, line 30 to page 10, line 18, page 11 line 4 to page 14, line 14, page 37, line 16 to page 38, line 17, and page 44, lines 16 to 18.

The withdrawal of claims 55-58 from consideration is moot in view of the cancellation of these claims and the agreement at the interview that the combined use of brain-derived neurotrophic factor and a bone morphogenic protein inhibitor or their encoding nucleic acids could be properly claimed.

The rejection of claims 28-30, 33-37, and 44-46 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed.

In particular, it is the position of the U.S. Patent and Trademark Office ("PTO") that claims directed to the use of brain-derived neurotrophic factor or a nucleic acid encoding that factor has not been shown by itself to be effective in treating Huntington's Disease. In making this rejection, the PTO has noted that the combination of brain-derived neurotrophic factor and a bone morphogenic protein inhibitor, like noggin, are effective in treating Huntington's Disease, as evidenced by the significant deceleration in motor degeneration and enhanced survival (see page 12, lines 16-21). Having limited the claims to the combined use of brain-derived neurotrophic factor and a bone morphogenic protein inhibitor or their encoding nucleic acids, it is submitted that, by the PTO's own acknowledgement, such claims are no longer susceptible to a non-enablement rejection. Accordingly, the rejection under 35 U.S.C. § 112 (1st para.) should be withdrawn.

The rejection of claims 1-5 and 13-17 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,071,889 to Weiss ("Weiss") is respectfully traversed.

Weiss teaches a method of inducing proliferation of a multipotent neural stem cell by administering various growth factors as proteins *per se* or as nucleic acids encoding

such proteins. Although Weiss lists BDNF amongst numerous other growth factors as being suitable for carrying out the subject procedure, there is no evidence of what growth factors might specifically be competent to cause directly infected subependymal cells to migrate out into the striatum, and hence to differentiate into neuronal cells, no establishment of an appropriate means of delivery, no assessment of whether neurons or glia might be generated through this approach, no indication of what neuronal phenotypes might be induced, no specific evidence that medium spiny neurons of the caudate and putamen might be so induced, no indication of whether newly induced neurons might extend fibers to efferent targets, no indication that any such neurons so induced and integrated might assume functional competence, no assessment of what growth factors or combinations thereof might be sufficient to achieve therapeutic endpoints, and no assessment or prediction of what appropriate disease targets for such strategies might be. Overall, Weiss fails to posit, specify or prove how growth factor addition to the adult brain might cause the specific addition of medium spiny pallidal projection neurons to the adult caudate nucleus and putamen.

Weiss identifies numerous conditions which might be treatable with the described procedure; however, there is no suggestion that the addition of medium spiny neurons can be induced. Furthermore, nowhere does Weiss suggest the use of a bone morphogenic protein inhibitor or a nucleic acid encoding it. Thus, Weiss cannot anticipate (or render obvious) the claimed method of inducing addition of medium spiny neurons in post-natal and adult brain.

Accordingly, the rejection based on Weiss alone should be withdrawn.

The rejection of claims 1, 6, 13, and 18 under 35 U.S.C. § 103(a) for obviousness over Weiss in view of U.S. Patent No. 5,965,440 to Reeves is respectfully traversed, because Reeves does not overcome the above-noted deficiencies of Weiss.

In view of all of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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